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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,486	12/27/2005	Haruo Sugiyama	283629US0PCT	6317

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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

NOTIFICATION DATE	DELIVERY MODE
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03/02/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/562,486	Applicant(s) SUGIYAMA, HARUO	
	Examiner Ron Schwadron, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
 4a) Of the above claim(s) 17-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____. |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/10/08 and 5/29/08 and 3/27/06 and 10/21/09 and 11/23/09.

1. Applicant's election with traverse of Group I, HLA tetramer technique and SEQ. ID. No. 2 in the reply filed on 8/18/08 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because of the following reasons. Restriction in the instant application was required under 35 U.S.C. 121 and 372. This application contains the inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The inventions listed as Groups I-V in the previous Office communication do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The inventions lack a special technical feature because the inventions are obvious or anticipated as per indicated in the JPO search reports supplied in the instant application and because of the art rejections enunciated in the instant Office action.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 17-49,59-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/18/08.

3. Applicant's election with traverse of the method of claim 1 in the reply filed on 10/23/09 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because of the following reasons. Regarding applicants comments, it would place an undue burden upon the Examiner to search additional nonelected species. The inventions lack a special technical feature because the inventions are obvious or anticipated as per indicated in the JPO search reports supplied in the instant application and because of the art rejections enunciated in the instant Office action.

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 50-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/23/09.

5. The disclosure is objected to because it contains an embedded hyperlinks and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable code. See MPEP § 608.01.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-6,8-14,16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", *Vas-Cath, Inc. V. Mahurkar*, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed inventions.

The instant claims encompass use of mutant and variant peptides (see specification, page 23, first paragraph) wherein the identity of said peptides is not disclosed in the specification and the amino acid sequence of such mutant/variants is unpredictable. With the exception of the specific WT1 peptides disclosed in the specification, the skilled artisan cannot envision the detailed structure of the encompassed mutants and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. In the instant application, the amino acid itself or isolated protein is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co.*

Lts., 18 USPQ2d 1016. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd.*, 18 U.S.P.Q.2d 016 (Fed. Cir. 1991). Attention is also directed to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein is stated: "The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA." See *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

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8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-12,16 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNeill et al. (WO 02/28414) in view of Altman et al.

McNeill et al. teach assays for the detection in cancer patients of T cells that respond to WT1 peptides(see pages 5,6 47,51-52).McNeill et al. teach use of such techniques for monitoring the effectiveness of immunization/therapy in said patients (see pages 5,6 47,51-52) wherein the immunization refers to immunization with WT1 peptides (see page 36). McNeill et al. teach that patients that display a higher T cell response are expected to show a greater response to therapy (see page 47, last sentence). McNeill et al. disclose that one of the peptides used in said method is that of SEQ ID NO:2 (see page 2, last paragraph continued on next page). McNeill et al. do not specifically teach the method steps of claim 1 using the assay of claim 1, step (b) or use of the HLA tetramer method. In view of the teachings of McNeill et al. that patients that display a higher T cell response are expected to show a greater response to therapy, a routineer would have screened for such patients using art known techniques and wherein a baseline response (aka from normals) would be required to differentiate higher from normal responders. Altman et al. teach a convenient assay for the identification of antigen specific T lymphocytes wherein CTL precursors are measured using a "HLA tetramer method" (see abstract, pages 94-96). McNeill et al. disclose that T cell responses are measured using biological samples from the test subject (see page 51, last paragraph). The assay of Altman et al. uses the method of claim 5/6 wherein the tetramer contains HLA-A2 antigen (see Figure 1). The HLA tetramer would be matched to the HLA of the tested patient. HLA tetramer/WT1 peptide complex binding to T cells would be measured using flow cytometry as per the method of Altman et al. (see Figure 1). A routineer would empirically determine the desired response that constituted a "higher frequency". The CTL precursors are effector cells (see page 95). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was

made to have created the claimed invention because McNeill et al. teach assays for the detection in cancer patients of T cells that respond to WT1 peptides and use of such techniques for monitoring the effectiveness of immunization/therapy in said patients and that patients that display a higher T cell response are expected to show a greater response to therapy wherein a routineer would have screened for such patients using art known techniques and wherein a baseline response (aka from normals) would be required to differentiate higher from normal responders whilst Altman et al. teach a convenient assay for the identification of antigen specific T lymphocytes wherein CTL precursors are measured using a "HLA tetramer method". One of ordinary skill in the art would have been motivated to do the aforementioned because McNeill et al. teach assays for the detection in cancer patients of T cells that respond to WT1 peptides and use of such techniques for monitoring the effectiveness of immunization/therapy in said patients and that patients that display a higher T cell response are expected to show a greater response to therapy whilst Altman et al. teach a convenient assay for the identification of antigen specific T lymphocytes wherein CTL precursors are measured using a "HLA tetramer method".

10. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNeill et al. (WO 02/28414) in view of Altman et al. as applied to claims 1-12,16 above, and further in view of Nagai et al.

The previous rejection renders obvious the claimed method except for use of the markers recited in claim 13. Nagai et al. teach that effector T cells are CD8+/CD45RA+/CD27- (see page 197, second column last paragraph) Said cells are identified using antibodies against said markers. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because the previous rejection renders obvious the claimed method except for use of the markers recited in claim 13 whilst Nagai et al. teach that effector T cells are CD8+/CD45RA+/CD27- wherein a routineer would have used said markers to further characterize the cells identified in the method of Altman et al. (for example as per Figure 1). One of ordinary skill in the art would have been motivated to do the aforementioned to identify effector T cells in the responding cells identified by the method of Figure 1 because said cells mediate T cell effector function.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/

Ron Schwadron, Ph.D.

Primary Examiner, Art Unit 1644